Testimony of Dr. Jane Teta

before the Illinois House Environment Committee

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Good afternoon. My name is Dr. Jane Teta. I am a principal epidemiologist at Exponent, a scientific consulting company, based in Menlo Park, CA. Both my master's and doctoral degrees were received from Yale university in biostatistics and chronic disease epidemiology, respectively. I have been an occupational epidemiologist for 40 years, 35 of which have included the conduct of ethylene oxide worker cancer studies and risk assessments and which include numerous publications in peer reviewed scientific journals. I am here at the request of Medline to offer my opinions regarding the findings of ethylene oxide worker studies and how and why these findings are inconsistent with the U.S. EPA 2016 ethylene oxide cancer risk assessment.

Let me jump to the main point of my remarks. The EPA assessment is flawed and it should not be used to predict cancer risks of any kind. I'll outline three reasons why I hold this opinion:

1. The EPA report used a faulty exposure-response model to predict cancer risk
2. The report included estimated worker exposure values that were implausibly lower in early years of the sterilant industry,
3. The report used only one study in their statistical analysis, ignoring contradictory research.

As a result, the American Chemistry Council has recently submitted a request for correction under the Information Quality Act describing in detail the flaws in the EPA assessment and its incorrect application in the 2014 NATA maps.

Now let's focus in on what we have learned from human studies of ethylene oxide workers. There are a large number of such studies published over a forty-year period conducted by scientists in the U.S. and in numerous European countries. There is no pattern of increases for any type of cancer among the 13 studies, which included over 34,000 ethylene oxide workers. Any isolated increased risks seen are of small magnitude or based on small numbers and there is no clear increase in risk with greater exposure. As a result, it is generally agreed among scientists that the human studies of ethylene oxide do not provide sufficient evidence of carcinogenicity. The EPA document also agrees, stating, "…the epidemiologic evidence does not provide conclusive proof of causality."

The limited human evidence and the one relied upon by the EPA in their assessment comes from a large study of sterilant plant workers conducted by the National Institutes of Occupational Safety and Health (NIOSH). The evidence of cancer risk was limited, and the conclusions of the study authors were not definitive. The NIOSH worker communication noted that their suspect findings of increased risk were related to "very high levels" of EO exposure, which existed over 40 years ago before current safety practices and exposure limits were implemented.

The other most informative EO worker study, and one of many I co-authored, includes men producing and using ethylene oxide in Union Carbide Corporation chemical plants from 1925. There is ample evidence of high exposures in the early years of this industry. A ten-year update has just been completed and includes follow up from 1940 to 2013 – that's 73 years. If there were a causal link to cancer at these levels, it would have been identified by now.

The study, with follow up through 2003 showed no evidence of cancer increases but was ignored in the EPA exposure-response assessment, despite its availability at the time.

In addition to reliance on a single study, the EPA risk estimate was derived from the selection of a faulty model of the relationship between ethylene oxide exposure and risk. This is the most influential decision made in the EPA analysis, because it modeled the NIOSH sterilant study data using a relationship called "supralinearity", which means assuming risk increases faster in the low exposure range than in the higher exposure range, resulting in an exaggerated risk estimate at low exposures. This is contrary to a discussion in the EPA document itself, which states it is "highly plausible that the dose-response relationship over the endogenous range is sublinear …", quite the opposite of the model selected. This is particularly important in that EO generation from normal human biology is equivalent to inhaling an EO dose that is approximately 19,000 times higher than the EPA's projected one-in-a-million health risk. The supralinear model is also contrary to the expected mechanism of carcinogenicity, to what is seen in the epidemiology studies, including the NIOSH worker communication conclusion, and to the mode of action of ethylene oxide in the human body. Had the EPA used a more traditional exposure-response model, which fits the data equally well, there would have been a very different and more plausible result.

The U.S. EPA's cancer risk assessment guidelines caution that "a steep slope [i.e., supralinear] also indicates that errors in an exposure assessment can lead to large errors in estimating risk." This is relevant to the EPA ethylene oxide assessment because the NIOSH exposure model has a much higher level of

uncertainty between the late 1930s and 1978 given there was no sterilant worker exposure data prior to 1976 to independently validate the model. The NIOSH exposure model incorrectly predicted that exposures would be lower in the early years of the sterilant industry than in 1978 for the most exposed jobs (e.g. sterilizer operator). In general, underestimating exposures will overestimate risk.

The EPA document concludes that lifetime levels as low as 0.1 ppt pose a cancer risk. In addition to being contrary to the findings of the epidemiology studies of workers exposed to much higher levels, this level is so small as to suggest normal human activities are a health concern. For example, the levels of ethylene oxide in the ambient air, naturally produced by the human body, and the levels exhaled in human breath are hundreds if not thousands of times greater than the minute exposure level that EPA calculates as posing a risk to humans.

The EPA cancer risk value is an implausible exaggeration and strains scientific credibility. It is, therefore, scientifically incorrect to draw inferences about cancer risks to populations potentially exposed to ethylene oxide using the EPA cancer risk number, as has occurred in the NATA 2014 assessment.